

REMARKS

After entry of this Amendment, the pending claims are: claims 1 and 13-18. The Office Action, dated April 27, 2010, has been carefully considered. Claims 5, 9, 10, 12 and 21 have been canceled. Claims 2-4, 6-8, 11, 19 and 20 were previously canceled. Independent claim 1 has been amended. Support for the amendments to claim 1 can be found throughout the Specification and Drawings and specifically in paragraph No. 31. Accordingly, no new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following remarks is respectfully requested.

In the Office Action, dated April 27, 2010, the Examiner:

- rejected claims 1, 5 and 12 under 35 U.S.C. 103(a) as being unpatentable over U.S. Published Patent Application No. 2004/0106998 to Ferree (“Ferree”) in view of U.S. Patent No. 5,333,347 to Stranders (“Stranders”) in further view of U.S. Published Patent Application No. 2003/0208273 to Eisermann *et al.* (“Eisermann”);
- rejected claims 9 and 10 under 35 U.S.C. 103(a) as being unpatentable over Ferree in view of Stranders in further view of Eisermann in further view of U.S. Patent No. 5,762,410 to Lutz (“Lutz”); and
- rejected claims 13-18 under 35 U.S.C. 103(a) as being unpatentable over Ferree in view of Stranders in further view of Eisermann in further view of U.S. Published Patent Application No. 2002/0052656 to Michelson.

Applicants respectfully traverses these rejections.

INDEPENDENT CLAIM 1

Independent claim 1 is directed to an intervertebral implant comprising a central axis, an upper

section, suitable for laying onto a base plate of a vertebral body lying above, and a lower section suitable for laying onto a cover plate of a vertebral body lying below, and recites, *inter alia*, as follows (emphasis added):

the *upper section* has ... a bottom surface and a first projection extending from the bottom surface, the first projection including a first drill hole ... the *lower section* has ... a top surface and second and third projections extending from the top surface, the second and third projections including second and third drill holes ... and a *frame shaped, central joint section* located between the upper and lower sections so that the upper section is moveable with respect to the lower section, the central joint section including a central bore and ***first, second, third and fourth drill holes***, the first projection extending from the bottom surface of the upper section being receivable within the central bore formed in the central joint section, the central joint section being receivable between the second and third projections extending from the top surface of the lower section so that a ***first axle*** is receivable in the first and second drill holes formed in the central joint section and the first drill hole formed in the first projection, a ***second axle*** is receivable in the third drill hole formed in the central joint section and the second drill hole formed in the second projection and a ***third axle*** is receivable in the fourth drill hole formed in the central joint section and the third drill hole formed in the third projection; and a removable insert for temporary blocking movement of the upper and lower sections such that the insert maintains the upper and lower sections, measured at their ventral side areas, at a fixed distance from each other, the insert including a lower end and an upper end, the upper end being receivable in the first depression, the lower end being receivable in the second depression, the first and second depressions being dovetail guides that taper from the ventral side areas towards the dorsal side areas and the upper and lower ends on the insert being arranged complementary to the dovetail guides, ***the insert being coupled to one of the upper and lower sections by a screw; wherein an end of the second axle is spaced from an end of the third axle by a gap.***

Ferree discloses an intervertebral implant including upper and lower plates. As admitted by the Examiner, Ferree does not disclose, teach or suggest the features recited above. *See Office Action*, dated April 27, 2010, pages 4 and 5. As such, the Examiner relies on Stranders and Eisermann for disclosing those features. *See Office Action*, dated April 27, 2010, pages 5-8.

Stranders discloses an apparatus for cleaning the inner surfaces of the front and rear windows of an *automobile*. The apparatus includes a handle (1) and a cleaning part (2) wherein the handle (1) is connected to the cleaning part (2) via a knuckle joint (5). In use, the knuckle joint (5) provides limited mobility of the handle (1) relative to the cleaning part (2).

Applicants respectfully submit that it would not be obvious for one of ordinary skill in the art to utilize the *automotive* knuckle joint of Stranders in the *artificial spinal disc* of Ferree. First and foremost, Stranders does not disclose a first, second and *third* axle *wherein an end of the second axle is spaced from an end of the third axle by a gap*; rather, Stranders at most discloses a first and second axle. As shown in the figure in the Office Action, Stranders discloses at most a unitary “second” axle which the Examiner has labeled both “second” and “third” axles (indicating each half as being a single element). *Office Action*, dated April 27, 2010, pages 3.

Next, the automotive knuckle joint of Stranders is designed for operation under different conditions – the claimed invention is designed for operation and articulation within the spinal column of the human body; in contrast, the wiper of Stranders is designed for operation and articulation while cleaning a windshield by hand. Further, an intervertebral implant typically experiences large forces associated with the human spine. In addition, an intervertebral implant typically allows sufficient rotational movement of the upper and lower sections (i.e., plates or members). A windshield wiper is not concerned with such issues or forces. The ordinary person of skill in the art of making intervertebral implants would not look to handheld windshield wipers for design features.

Moreover, Stranders is completely silent as to the sufficiency of using the disclosed knuckle joint in an intervertebral implant. Stranders is also completely silent on the ability for the recited joint to withstand the necessary forces experienced within an intervertebral implant. Further, the examiner has not *clearly articulated any reasoning with some rational underpinning* to explain why one of ordinary skill in the art of intervertebral implants would look to windshield wipers when designing spinal implants.

Third, Applicants respectfully submit that, if for some strange reason the ordinary intervertebral implant designer did look towards Strander's windshield wiper for design features, there is no reason for implementing an implant comprising four drill holes and three axles in the particular manner as recited by the claims. Specifically, there is no reason for implementing an implant comprising a first drill hole formed in a first projection extending from the bottom surface of the upper section, second and third drill holes formed in second and third projections, respectively, extending from a top surface of the lower section, and first, second, third and fourth drill holes formed in a frame shaped, central joint section wherein the first projection is received within a central bore formed in the frame and the frame is received between the second and third projections so that a first axle is received in the first and second drill holes formed in the frame and the first drill hole formed in the first projection, a second axle is received in the third drill hole formed in the frame and the second drill hole formed in the second projection and a third axle is received in the fourth drill hole formed in the frame and the third drill hole formed in the third projection.

Applicants respectfully submit that in order to reach a proper determination of obviousness under 35 U.S.C. § 103, the Examiner must step backward in time and into the shoes worn by a hypothetical

“person of ordinary skill in the art” when the invention was unknown and just before it was made. *See M.P.E.P. § 2142*. This puts the examiner in the time period in which possibly hundreds of intervertebral implant patents have been issued, not a single one of which the examiner has found to include the recited joint. Next, knowledge of the Applicants’ disclosure must be put aside. *See Id.* Although the tendency to resort to “hindsight” based upon the Applicants’ disclosure is often difficult to avoid, impermissible hindsight must nonetheless be avoided. *See Id.*

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. *See M.P.E.P. § 2142*. The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *See In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006); *see also KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (quoting *In re Kahn* with approval). The Supreme Court of the United States affirmed this reasoning in *KSR*, stating that the analysis supporting a rejection under 35 U.S.C. §103 should be made explicit. *KSR*, 127 S.Ct. at 1741. Moreover, this Board has followed suit and has observed that the Supreme Court in *KSR* “did not dispense with the premise that a conclusion of obviousness requires some explicit rationale for practicing the claimed subject matter:”

[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. . . because inventions in most, if not

all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Ex parte Coppeta, Appeal 20084898, decided February 5, 2009 (quoting *KSR*, 127 S.Ct. at 1741); *see also Ex parte Zhu*, Appeal 20082138, decided May 19, 2008 (reversing the rejections under 35 U.S.C. §103 because the examiner provided no “apparent reason to combine the known elements in the fashion claimed”); *Ex parte McQuiston*, Appeal 20083224, decided March 6, 2009 (reversing the rejection under 35 U.S.C. §103 because the examiner failed to provide an obviousness rationale); *Ex parte Barnes*, Appeal 20074114, decided Jan. 22, 2009 (reversing the rejection under 35 U.S.C. §103 because the examiner failed to “provide any reason with rational underpinning to explain why [the feature of the claimed invention] would have been obvious”).

In the present application, the Examiner supports his combination of Stranders with Ferree by stating that the joint of Ferree and the universal joint as taught by Stranders are equivalent for their use in the joints and connections art and the selection of any of these known equivalents to join or connect two parts would be within the level of ordinary skill in the art.

Applicants respectfully submit that the Office Action’s justification for combining Stranders with Ferree does not constitute a ***clear articulated reasoning with some rational underpinning*** for supporting a legal basis for sustaining an obviousness rejection. Rather, the purported justification is merely an unsupported broad conclusory statement, which is precisely the type of justification that the MPEP and courts warn against. It is respectfully submitted, that the Examiner is undertaking and

relying on impermissible hindsight reconstruction. Applicants respectfully submit that the Examiner has picked and chosen individual elements from assorted prior art references and has combined the selected elements into a theoretical device that includes all of the elements of the device of claim 1 in a way that one having ordinary skill in the art at the time of the invention would never have combined such elements. The Examiner has provided no support, reasoning and/or evidence for combining the prior art references in this manner, other than the combination would disclose each and every limitation of pending independent claim 1. *See Grain Processing Corp. v. American Maitze-Products Corp.*, 840 F.2d 902 (Fed. Cir. 1988) (one cannot simply use the Applicant's disclosure as a blueprint to pick and choose among the individual elements of assorted prior art references in order to combine the right references in the right way to achieve the Applicant's claimed invention).

It is respectfully submitted that without the benefit of the Applicants' disclosure, it would not be obvious for one of ordinary skill in the art to redesign the intervertebral implant of Ferree to include the recited joint as taught by Stranders and any unsupported broad conclusory statement to the contrary to support such a conclusion of obviousness cannot be sustained. Moreover, even if one would have endeavored, for some strange reason, to combine the joint of Stranders with the intervertebral implant of Ferree, the result would not be the invention as claimed. In contrast, the result would be a *two axle* joint, rather than a system having *three axle, wherein an end of the second axle is spaced from an end of the third axle by a gap*, as recited by the claims.

Accordingly, Applicants respectfully submit that the Examiner's combination of Stranders with Ferree to render obvious the claimed invention is in error, and consequently the rejection under 35

U.S.C. § 103(a) cannot stand. Withdrawal of the present rejections and allowance of independent claim 1 is respectfully requested.

In an effort to expedite prosecution of the present application, Applicants respectfully submit that independent claim 1 has amended to recite, *inter alia*, a removable insert for temporary blocking movement of the upper and lower sections such that the insert maintains the upper and lower sections, measured at their ventral side areas, at a fixed distance from each other, the insert including a lower end and an upper end, the upper end being receivable in the first depression, the lower end being receivable in the second depression, the first and second depressions being dovetail guides that taper from the ventral side areas towards the dorsal side areas and the upper and lower ends on the insert being arranged complementary to the dovetail guides, the insert being coupled to one of the upper and lower sections by a screw.

As admitted by the Examiner, the combination of Ferree and Stranders does not disclose, teach or suggest a removable insert for causing temporary blocking movement of the upper and lower sections, the ventral sides of the upper and lower sections including first and second depressions, the insert including a lower end and an upper end, the upper end being receivable in the first depression, the lower end being receivable in the second depression. *See Office Action*, dated April 27, 2010, page 7. Rather, the Examiner further relies on Eisermann for disclosing a removable insert for temporary blocking movement of the upper and lower sections.

Eisermann discloses an intervertebral prosthetic joint 30 including a first articular component 32 and a second articular component 34. The articular components 32, 34 including a channel 57 for

engaging a corresponding portion of a surgical instrument (not shown) to aid in the manipulation and insertion of the prosthetic joint 30. The surgical instrument holding the articular components 32, 34 at a predetermined orientation and spatial relationship relative to one another during manipulation and insertion of the prosthetic joint 30, and to release the articular components 32, 34 once properly positioned between the adjacent vertebrae.

Applicants respectfully submit that there is no disclosure, teaching, or suggestion in Eisermann, either alone or in combination with Ferree and Stranders, of a removable insert for temporary blocking movement of the upper and lower sections *wherein the insert is coupled to one of the upper and lower sections by a screw*. Rather, the so-called insert in Eisermann is a surgical instrument that engages a channel formed in the articular components 32, 34 of the prosthetic joint 30.

Therefore, Applicants respectfully submit that claim 1 is allowable over Ferree, Stranders and Eisermann for at least these reasons. Withdrawal of this rejection and allowance of claim 1 is respectfully requested.

Furthermore, as claims 13-18 all depend from independent claim 1, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 13-18 is also respectfully requested.

With respect to claims 13-18 which were rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree in view of Stranders in view of Eisermann and in further view of Michelson, it is respectfully submitted that Michelson does not overcome the short comings of Ferree, Stranders and Eisermann. Michelson was cited for the proposition that it would be obvious to incorporate at least two

holes in the upper and lower section for receiving bone fixation devices. Without addressing the merits of this argument and/or the combination, it is respectfully submitted that, for at least the above-identified reasons, neither Ferree, Stranders, Eisermann nor Michelson, either alone or in combination, disclose, teach or suggest all of the limitations of dependent claims 13-18 and, specifically, the above-listed features of claim 1. Thus, it is respectfully submitted that dependent claims 13-18 are allowable over Ferree, Stranders, Eisermann and Michelson. Withdrawal of this rejection and allowance of dependent claims 13-18 is respectfully requested.

CONCLUSION

Based upon the above-listed amendments and remarks, Applicants respectfully submit that the present application, including claims 1 and 13-18, is in condition for allowance and such action is respectfully requested.

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

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In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

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Respectfully submitted,

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